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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/846,808	05/01/2001	David H. Walker	D6311	5870

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EXAMINER	
BASKAR, PADMAVATHI	
ART UNIT	PAPER NUMBER
1645	8

DATE MAILED: 12/10/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/846,808	WALKER ET AL.	
	Examiner	Art Unit	
	Padmavathi v Baskar	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 October 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) *9-13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-13* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4/5* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Applicant's response to restriction filed on 10/7/02 is acknowledged. No claims have been canceled. No claims have been added or amended. Claims 1-13 are pending in the application.

Priority

2. Applicant's claim for domestic priority under 35 U.S.C. 119(e) to provisional application 60/201,035, 5/1/2000 is acknowledged.

Information Disclosure Statement

3. Information Disclosure Statement filed on 3/08/02 and 6/11/02 (Paper # 4 and 5) is acknowledged and a signed copy is attached to this Office action.

Election

4. Applicant's election of Group I claims 1-8 with traverse with respect to SEQ.ID.NO: 1 in Paper No 7 (10/7/02) is acknowledged. Therefore, claims 9-13 have been withdrawn from consideration as a non-elected invention.

It is noted that the restriction of one SEQ.ID.NO is not an election of species. The examiner made it clear on the record in paper # 6 (9/9/02) paragraph 3 that the disclosed sequences are considered as patentably distinct and different inventions since each SEQ.ID.NO is distinct and given a specific sequence identification number i.e., SEQ.ID.NO: 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 20 and 21 containing different amino acids.

The traversal is on the ground(s) that applicant asserts that (1) the protein species in group I are integrally related and SEQ.ID.NOs: 1-13 and 20-21 represent the products of p28 genes within a single multigene locus in E.chaffeensis, (2) Besides being related by significant

sequence identity, the genes in the p28 locus function together to escape the immune response (3) the expression of genes is varied and in turn vary presentation of P28 antigens and (4) search of the prior art would not unduly burden the examiner.

This is not found persuasive because (1) applicant has not shown how these proteins are integrally related and to what? As applicant rightly pointed out that SEQ.ID.NOs: 1-13 and 20-21 represent various products of p28 genes. Whether these genes are within a single multigene locus is not irrelevant because each gene encodes a different product, i. e., SEQ.ID.NO 1 or 2 or 3 etc. (2) Further, the examiner has established that the Inventions SEQ ID NO: 1-13, 20 and 21 are unrelated and have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions; represent structurally different polypeptides and the polynucleotides encoding them. Therefore, where structural identity is required, such as for hybridization or expression, the different sequences have different effects. Thus, each sequence is unique and patentably distinct and each sequence has a different structure with specific amino acid or nucleic acid and is identified by a specific SEQ.ID.NO. Immune response as a whole is not a single function. Immune response is mediated by various cell types namely T cells, B-cells, Monocytes, eosinophils etc and each cell respond to a protein differently in mediating either antibody response or cell mediated response. (3) Again applicant correctly identifies that the expression of genes is varied and in tum presentation of P28 antigen varies structurally and functionally resulting in various sequences (SEQ ID NO: 1-13, 20 and 21). (4) Further, the restriction of sequences has acquired a separate status in the art as a separate subject for inventive effect and requires independent searches. The search for each of the above inventions is not co-extensive particularly with regard to the literature search. A reference, which would anticipate the invention of one SEQ.ID.NO, would not necessarily anticipate or make obvious any of the

other SEQ.ID.NO. Moreover, as to the question of burden of search, classification of subject matter is merely one indication of the burdensome nature of the search involved. The literature search and sequence search, particularly relevant in this art, is not co-extensive and is much more important in evaluating the burden of search. Burden in examining materially different groups having materially different issues also exist. Restriction is deemed proper because these products appear to constitute patentably distinct inventions.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated polynucleotide (cDNA) which encodes SEQ.ID.NO 1, vector and a host cell comprising the same does not reasonably provide enablement for a DNA (i.e., gene additionally, encompasses many polynucleotides, which are not described) encoding one or more proteins, an isolated DNA which hybridizes to the gene and isolated DNA differing from the genes in codon sequence due to the degeneracy of the genetic code (i.e., variants or fragments), vectors capable of expressing the gene and host cell transfected the gene. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Instant claims are evaluated for scope of enablement based on the Wands analysis. Many of the factors regarding undue experimentation have been summarized in In re Wands, 858 F.2d 731,8 USPQ2d 1400 (Fed.Circ.1988) as follows:

(1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

The specification is not enabling for the claimed invention because the specification does not provide sufficient guidance as to how an artisan would have made all the polynucleotides sequences, vectors, and host cells expressing all the claimed polynucleotides sequences claimed above and would have used those without undue experimentation. The specification does not enable any gene that hybridizes under the conditions of claim 1, would enable a functional P28 protein.

It is noted that the specification, in example 9 provides description of an isolated polynucleotide, which encodes SEQ. ID.NO: 1, encompassed by the claimed invention. However, the specification does not provide how would an artisan have made the innumerable polynucleotides that encode these fragments or polypeptides, and even if one had to assume that using various molecular biology techniques described in the specification an artisan would have been able to make these polynucleotides, would all the polypeptides encoded by the isolated polynucleotides have had any specific functions? Additionally, in the absence of any function, what would have been the use of making all these polynucleotides, expression systems comprising these polynucleotide segments, host cells comprising these polynucleotide expression systems, producing the polypeptides encoded by these polynucleotides or preparing a number of host cells expressing these polynucleotides? Moreover, screening of a library with

a full length or fragments of a given polynucleotide under disclosed hybridization conditions could produce numerous polynucleotide molecules. There will be no way of knowing what sequences will be obtained by this method and what would have their function or use been, if any. The specification does not provide any guidance as to how an artisan would have determined what would have been the function of all these polynucleotides and how would this multitude of polynucleotide would have been used or for what use.

It is concluded that the specification is not enabling for the claimed invention as filed and an artisan would not have been able to practice the invention without undue experimentation. Therefore, limitation of the scope of the invention is to an isolated polynucleotide sequence encoding (cDNA) SEQ.ID.NO: 1, vector and a host cell is proper.

Claim Rejections - 35 USC 112, second paragraph

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-6 are drawn to a DNA, which can mean a gene. According to Genes IV (Lewin et al, Oxford University Press, page 810, 1990), a gene is defined as "the segment of DNA involved in producing a polypeptide chain; it includes regions preceding and following the coding regions (leader and trailer) as well as intervening sequences (introns) between individual coding segments (exons)." From the teachings of the specification, however, the nucleic acid sequences coding for the P28 protein appear to be limited to the specific coding regions, and do

not include expression control elements that fall under the definition of a DNA i.e., gene. Accordingly, the claims are indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. .

Claim 1 is rejected as being vague because step (b) appears to be claiming a complementary sequence (for hybridization), which does not encode a protein, as the preamble requires.

Applicant is advised to amend claim 5 to recite as "a vector comprising the polynucleotide that encodes the amino acid sequence SEQ.ID.NO: 1"

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Ohashi et al 1998, (Infec.Immun, 66; 132-139).

Claims 1-8 are directed to a DNA that encodes P28 protein from E.chaffeensis wherein said protein has an amino acid sequence SEQ.ID.NO: 1, vector and host cell.

Ohashi et al disclose the outer membrane protein P28 (see abstract). The prior art discloses an isolated DNA (encoding the P28 protein was cloned in to vector pCRII and expressed in expression vector pET 29 and amplified in E.coli (see page 133, left column, first paragraph). The disclosed DNA encodes the P28 protein. The encoded p28 protein is 100%

identical with the claimed SEQ.ID.NO: 1 (see the sequence alignment in Accession U72291 AF021338). The prior art anticipated the claimed invention.

10. Claims 1-8 are rejected under 35 U.S.C. 102(a) as being anticipated by Yu et al 2000 (Accession AF 230642 and Gene 2000, 248; 29-68).

Claims 1-8 are directed to a DNA that encodes P28 protein from E.chaffeensis wherein said protein has an amino acid sequence SEQ.ID.NO: 1, vector and host cell.

Yu et al et al disclose the outer membrane protein P28 (see abstract). The prior art discloses an isolated DNA encoding the P28 protein was cloned in to Topo TA vector (see page 61-62) and the P28 proteins have been predicted (see figure 2). The disclosed DNA encodes the P28 protein. The encoded p28 protein is 100% identical with the claimed SEQ.ID.NO: 1 (see the sequence alignment in AF 230642). The prior art anticipated the claimed invention.

Status of claims

11. Claims 1-8 are rejected.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padma Baskar whose telephone number is (703) 308-8886. The examiner can normally be reached on Monday through Friday from 6:30 AM to 4 PM EST

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Padma Baskar Ph.D

11/8/02.

LYNETTE R. F. SMITH
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